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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/778,496 | 02/07/2001 | David M. Lubman | UM-06106 | 8813 |

23535 7590 10/01/2003

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101 HOWARD STREET
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EXAMINER

MAHATAN, CHANNING

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1631

12

DATE MAILED: 10/01/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/778,496

Applicant(s)

LUBMAN ET AL.

Examiner

Channing S. Mahatan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6, 8-24 and 26-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 8-24 and 26-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3 Sheets.
- ☐ Interview Summary (PTO-413) Paper No(s): _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other:

DETAILED ACTION

APPLICANTS' ARGUMENTS

Applicants' arguments in Paper No. 10, filed 26 June 2003, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

CLAIMS UNDER EXAMINATION

Claims herein under examination are claims 1-6, 8-24 and 26-34.

Claims Rejected Under 35 U.S.C. § 103

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-6, 8-24, and 26-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chong et al. taken in view of Richmond et al. (High-throughput flow injection analysis-mass spectrometry with network delivery of colour rendered results: the characterisation of liquid chromatography fractions, Journal of Chromatography. 1999, Volume 835, pages 29-39).

Chong et al. describes profiling proteins of whole cell lysates wherein protein fractions are separated by non-porous reverse phase HPLC and analyzed using matrix-assisted laser desorption/ionization time-of-flight mass spectrometry (MALDI-TOFMS) (Abstract; page 1987, column 1, lines 5-7; and page 1993, Column 1, lines 6-10). The authors were able to distinguish

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protein profiles from malignant and normal breast epithelium cell lysates, giving different and distinguishable protein profiles of different cell types (page 1987, Column 1, lines 7-35).

Fractions were analyzed using MALDI-TOFMS to ascertain their molecular weights and observed protein expression (p 1987, Column 1, lines 36-37). Prior to MALDI-TOFMS analysis the cell lysates/sample were treated with external agents (p 1987-1989, "Matrix, substrate and sample preparation" section). Beckman System Gold HPLC utilized in this work includes a System Control Center display and keypad permitting the control of not only the device, but also external modules (page 1989, Column 1, lines 16-21). Chong et al. indicates that the Beckman System Gold® HPLC is "automated" by having "a programmable solvent delivery module with a dual-pump.... This module includes a System Control Center display and keypad which permits control of the pump and external modules directly (page 1989, column 1, lines 17-21), therefore, said element(s) of "automation" would have been inherently apparent in Chong et al. per the device utilized (Beckman System Gold® HPLC). Further, data was recorded and processed on a computer (page 1989, Column 2, lines 16-19). Chong et al. illustrate the MALDI-TOF mass spectra data obtained of malignant and normal whole cell lysates of the MCF-10 cell lines (page 1988; and page 1989, Column 2, lines 41-47). However, Chong et al. fails to indicate that protein abundance can be represented graphically as color intensity bands.

Richmond et al. describes an automated high-throughput flow injection analysis electrospray-mass spectrometry to analyze liquid chromatography fractions, wherein the liquid chromatography fraction data is rendered in color to provide a fast and easy inspection (Abstract). The authors illustrate and describe the methodology of displaying the liquid

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chromatography data as graduating color bands representing mass and intensity (page 34, beginning on the right column, line 14; Figures 2 and 3).

Thus, it would have been obvious to someone of ordinary skill in the art at the time of the invention to practice Chong et al., protein profiling of whole cell lysates wherein protein fractions are separated by non-porous reverse phase HPLC and analyzed using matrix-assisted laser desorption/ionization time-of-flight mass spectrometry (MALDI-TOFMS), with Richmond et al., graphical display of colour intensity bands representing (intensity/mass) from liquid chromatography information, since Richmond et al. states coloured computer screen pictures and 3D maps provide quick and easy way of delivering liquid chromatography data to laboratories (page 39, left column, lines 17-23).

Applicants' arguments that Chong et al. fails to teach/require: 1) "an automated sample handling apparatus configured to receive separated proteins from said reverse phase HPLC separating apparatus"; 2) "a mass spectroscopy apparatus configured to receive proteins from said automated sample handling apparatus"; and 3) the "protein profile maps display each protein as a separate band corresponding to the mass of the protein sample, wherein the intensity of the bands corresponds to the abundance of the protein" in Paper No. 8, filed 28 January 2003, and Paper No. 10, filed 26 June 2003, have been considered. However, in view of these arguments the instant claims are determined unpatentable over Chong et al. taken in view of Richmond et al., and these arguments are addressed above.

INFORMATION DISCLOSURE STATEMENT

Several references in the 'Information Disclosure Statement' (Paper No. 11, filed 26 June 2003) were not considered due to the absence of the said references and have been lined through

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accordingly. Should Applicants desire consideration the missing references a new 'Information Disclosure Statement' accompanied by full copies of references is requested.

No Claims Are Allowed.

EXAMINER INFORMATION

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 C.F.R. § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Channing S. Mahatan whose telephone number is (703) 308-2380. The examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward, Ph.D., can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner, Tina M. Plunkett, whose telephone number is (703) 305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

Date: *September 30, 2003*

Examiner Initials: *CSM*

Marianne P. Allen
MARIANNE P. ALLEN
PRIMARY EXAMINER
GROUP 1800
A41671